

# Cayuse IRB Initial Submission Guide

Tips to get you started:

Please plan to allow enough time for submission, review and approval of your study | If you are a new user, please complete the [Cayuse Access Request](#) (STEP 1) | Reference the UNT IRB [website](#) for Cayuse user guidance. | To begin submission, [Log in to Cayuse IRB](#) | Mozilla Firefox Brower is the preferred browser for Cayuse users | Email [CayuseAccess@unt.edu](mailto:CayuseAccess@unt.edu) for any questions regarding Cayuse access. | Email [untirb@unt.edu](mailto:untirb@unt.edu) with any questions regarding protocol submission.

Questions highlighted in RED either appear or display additional options when the Expedited/ Full Board path is selected **(Question CI.7)**

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**Directions:** Below is a listing of all the questions in the initial IRB Cayuse application. Please follow the question directions as they appear in Cayuse (shown in the left column of this document). On the right column, you will find tips and tricks to walk you through the application process.

## Core Info- Funding, Review Category

### CI.1 In what general discipline(s) is your proposed research with human subjects?

<ul style="list-style-type: none"> <li><input type="checkbox"/> UNT Dallas - if you are a researcher for UNT Dallas, please check this box and also which discipline your study falls under.</li> <li><input type="checkbox"/> Biological or clinical science (biomedical), e.g. nutrition and kinesiology.</li> <li><input type="checkbox"/> Social science, behavioral science, or education (SBER), e.g., consumer preference and psychology.</li> <li><input type="checkbox"/> Other - Describe the general discipline(s) of your proposed research with human subjects.</li> </ul>	<p>For more information visit <a href="#">UNT IRB website</a> or call Research Integrity Compliance Office at 940-565-4643.</p> <p>UNT Dallas Researchers, please ensure you check the UNT Dallas box AND the discipline your research qualifies under.</p>
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### CI.2 What kind of funding or support do you have for this study with human subjects?

<p>For any internal or external funding, please submit the statement of work or a project summary and provide the Proposal Number or Project ID Number for any external funding or the account number for any internal funding for this project.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Federal such as NSF, NIH, DoD, DoE, DoEd, etc.</li> <li><input type="checkbox"/> UNT program such as GREAT Grant, Seed Grant, Trio, Office of Research and Innovation, etc.</li> <li><input type="checkbox"/> Other type, such as private sources.</li> <li><input type="checkbox"/> None</li> </ul>	<p>Some funding agencies require additional training. View training requirements here: <a href="https://research.unt.edu/research-services/research-integrity-and-compliance/human-subjects-irb/training-and-education">https://research.unt.edu/research-services/research-integrity-and-compliance/human-subjects-irb/training-and-education</a></p>
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CI.3 Are you collaborating with another group such as a school, community association, government agency, etc.?

<p>Is IRB approval necessary, or being obtained elsewhere (domestically or internationally)? <a href="#">UNT Website - Multi-Institutional or Collaborative Research</a></p> <p><input type="checkbox"/> Yes</p> <ul style="list-style-type: none"> <li><input type="radio"/> Please attach supporting documentation, or IRB approval letters from other agencies.</li> <li><input type="radio"/> ATTACH</li> </ul> <p><input type="checkbox"/> No</p>	<p>If you will be collaborating on this project, please answer "yes" to this question and attach collaboration approval. "Approval" can come in one of the following forms:</p> <ol style="list-style-type: none"> <li>1. Local IRB approval letter from your collaborator's university for this project.</li> <li>2. A letter from your collaborator's university IRB, explaining that they do not consider your collaborator(s) to be engaged in Human Subjects Research.</li> <li>3. A completed IRB Authorization Agreement (IAA), also known as a reliance agreement. Please note, some universities will not enter an IAA for Exempt studies. If you are interested in exploring this option, please complete an IAA request form: IAA Request Form.</li> </ol> <p>An IAA is a document, signed by institution officials, permitting one institution's IRB to cede review (institution B) to another institution's IRB (institution A) for a particular study involving human participants. In this way, only one IRB reviews and approves human subject research activities for both institutions, avoiding duplicative review and regulatory oversight. This is sometimes referred to as a "reliance agreement."</p>
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CI.4 International Research

<p>Will any research you perform be conducted outside the United States?</p> <p><input type="checkbox"/> Yes</p> <ul style="list-style-type: none"> <li><input type="radio"/> Please explain where the research will take place.</li> </ul> <p><input type="checkbox"/> No</p>	
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## CI.5 International Research - Continued

**International research is subject to additional checks and requirements that inevitably extend review time. If you have an imminent travel date, please reach out to [UNTIRB@unt.edu](mailto:UNTIRB@unt.edu) to make the IRB aware.**

Please consult the [International Compilation of Human Research Standards website](#) to determine if your destination requires local ethics board approval for your type of study and, if needed, find the appropriate local ethics board. If you are collaborating with a local university, it is also advisable to consult that institution.

- Please upload **local ethics board approval** as required in the International Research SOP: [IRB SOP 17.01, International \(Transnational\) Research](#).

Note: This is required for all studies in countries that require local ethics board review AND/OR for studies considered to be reviewed at the Expedited or Full Board level.

- Please upload a **letter of cultural appropriateness** as required in the International Research SOP: [IRB SOP 17.01, International \(Transnational\) Research](#).

NOTE: This applies if local ethics board approval is NOT required, AND the study is considered to be for Exempt level review.

- For International Travel: (it is the PI's responsibility to make initial contact with Risk Management).**

Please contact [UNT Risk Management](#) for their guidance with international travel and UNT guidelines, and respond back to the IRB with your email confirmation for traveling to a low-risk location. Please include a Risk Assessment Report along with your travel confirmation email for traveling to a high-risk location.

**The IRB approval, when provided, is for permission to conduct human subjects research only and does not cover your requirements for international travel as a UNT employee or student.**

Please upload the UNT Risk Management Email confirming permission to travel in .PDF form.

**Note:** This is not the colorful risk assessment information sheet for the destination, but an email from UNT Risk Management stating you have permission to travel on UNT business.

CI.6 Languages other than English

<p>Will your study involve the use of any language other than English for informed consent forms, data collection instruments, or recruitment materials? <b>See the ('?') for more details ==&gt;</b></p> <p><input type="checkbox"/> Yes</p> <ul style="list-style-type: none"> <li><input type="radio"/> If you have answered "Yes" please submit the versions written in languages other than English along with a back-translation for each. Specify all languages other than English below:</li> </ul> <p>Please ensure all translated versions of materials are uploaded in their specific sections alongside the English versions. See the ('?') for more details ==&gt;</p> <p>Please upload proof of translator credentials in the space below. These can include but are not limited to:</p> <ul style="list-style-type: none"> <li><input type="radio"/> CV or resume of the translator.</li> <li><input type="radio"/> Certification of translation services.</li> </ul> <p><input type="checkbox"/> No</p>	<p>IRB SOP 17.01, <a href="#">International (Transnational) Research</a></p> <p><a href="#">IRB Policies and Procedures page</a></p> <p>Required translation materials include but are not limited to:</p> <ul style="list-style-type: none"> <li>• Recruitment - Section 3.</li> <li>• Study Instruments - Section 4.</li> <li>• Informed Consent - Section 8.</li> </ul>
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CI.7 Under which IRB review category would you consider that your study will fall?

**NOTE:** This form employs progressive logic which, if Exempt is selected, will direct you to a vastly shorter form. If your project is subsequently judged to be Expedited or Full Board review, a full new protocol will be required to be submitted, significantly delaying your application.

**See the ('?') for more details ==>**

- Exempt | **lowest** risk level | lower than minimal risk
  - Expedited | **middle** risk level | minimal risk (faster review time than full board specifically)
  - Full Board Review | **highest** risk level | higher than minimal risk
- Exempt

Please explain your reasoning, based upon the regulatory definitions. Please ensure the attestations below match your project precisely. If in doubt consult the [regulatory definitions](#) in the help text in the '?' to the right, or contact the UNT IRB at [untirb@unt.edu](mailto:untirb@unt.edu).

Affirm that your research study does NOT involve any of the below items. {If your research study DOES involve any of these, you MUST change the IRB review category accordingly.}

- Yes, I affirm that my research study:
- Does NOT involve any vulnerable populations such as children, prisoners, pregnant women, or mentally disabled persons.
- Does NOT involve any public disclosure of any identifiable data you collect placing the participants at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation.
- Does NOT involve data collection procedures other than surveys, educational tests, interviews, or observation of public behavior.
- Does NOT involve any sensitive subject matters such as: abortion, criminal activity, sexual activity, sexually transmitted diseases, prior diagnosis for mental health disorders, or victims of violence.
- Does NOT involve collection of data from voice, video, digital or image recording made for research purposes.  
NOTE: This **does not** apply to audio and video recordings used to ensure accuracy of transcription only, and that will not be used in publications or presentations. **e.g. in interviews.**
- Does NOT involve obtaining individually identifiable information from health care plans, health care clearinghouses, or health care providers.

- Expedited or Full Board (Category will be determined by the IRB)

NOTE: The term Expedited **does not mean the fastest review path** – it refers to being lower risk level and therefore slightly faster than *full board review specifically*.

Please explain your reasoning, based upon the [regulatory definitions](#).

**Full Board**

More than minimal risk studies, as determined by the IRB Chair. Also, any human subjects research study that does not fit into one of the federal categories for Exempt or Expedited.

**Expedited**

To qualify for review at an Expedited level, the study must be no more than minimal risk and fit in one of the federally designated [expedited review](#) categories ([45CFR46.110](#) and [21 CFR 56.110](#)).

- Analyses of voice recordings.
- Studies of existing pathological specimens with patient identifiers.
- Collection of blood samples, up to 550ml, from healthy, non-pregnant adults who weigh at least 110 pounds.
- Collection of data using physical sensors that are applied either to the surface of the body or at a distance with minimal risk.
- Research on characteristics, behavior, research surveys, interviews, focus groups, program evaluations, or quality assurance methods that do not fall into Exempt categories.

**Exempt**

To qualify for review at the Exempt level, the research must not be greater than minimal risk and must fall into one or more of the Exempt categories (45CFR46.104). Exempt reviews are conducted typically by only one reviewer within the Research Integrity and Compliance Office. Typically, no annual renewal is required to be submitted. Modifications must be submitted.

Evaluating the use of accepted or revised standardized tests.

- A program evaluation of pharmacy continuing education.
- Interviewing managers about a management style or best practice.
- Conducting a focus group about an experience or an opinion of a community program.
- Solving puzzles under various noise conditions.

## Personnel- PIs, Status, Training, Facilitator status, training, facilitator

### PERS.1 Identify your status as it applies to this IRB protocol.

<p>In order to serve as Principal (Lead) Investigator, you must be a <b>full-time UNT faculty member</b> or a full-time staff employee whose job responsibilities include conducting human subjects research. The IRB application <b>must be</b> submitted by the lead PI/supervising investigator (in the case of student projects).</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Faculty</li> <li><input type="checkbox"/> Staff</li> <li><input type="checkbox"/> Unaffiliated Researcher</li> </ul>	<p>Adjuncts or lecturers must either submit a letter from the Department Chair acknowledging their approval for the research submission, or a full-time faculty can serve as lead PI of your study for the IRB purposes.</p> <p><b>Unaffiliated Investigator definition:</b> Any researcher who is not</p> <ol style="list-style-type: none"> <li>1. UNT student</li> <li>2. UNT faculty member</li> <li>3. UNT staff member</li> <li>4. Not affiliated with any other institution which has an IRB.</li> </ol> <p>Individuals may collaborate with members of the UNT faculty and staff to conduct investigations of mutual interest.</p>
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### PERS.2 Principal Investigator (PI):

<p>Please enter the Principal Investigator for this research study. This page uses a <b>FIND PEOPLE</b> button to add personnel to your research study. If you cannot find someone from UNT you wish to add, they may not have requested Cayuse access. <a href="#">Please follow this link for information on how to request access to Cayuse.</a></p>	<p>In order to serve as PI, you must be a full-time faculty staff member who is PI eligible. A person holding any of the following academic ranks can serve as a Lead PI or Principal Investigator (Co-PI):</p> <ul style="list-style-type: none"> <li>• Professor.</li> <li>• Associate Professor.</li> <li>• Assistant Professor.</li> <li>• Librarian.</li> <li>• Associate Librarian.</li> <li>• Research Professor.</li> <li>• Research Associate Professor.</li> <li>• Research Assistant Professor.</li> <li>• Research Scientist IV.</li> <li>• Research Scientist III.</li> <li>• Research Scientist II.</li> </ul> <p>Others may request approval to serve as a Lead PI or Principal Investigator (Co-PI). For persons with the following job titles, Lead PI or Principal Investigator status may be requested. In order to be approved, a <b>letter of support from your department chair/leadership must be provided:</b></p>
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	<ul style="list-style-type: none"> <li>• Assistant Librarian.</li> <li>• Postdoctoral Research Associate.</li> <li>• Research Scientist I.</li> <li>• Director.</li> <li>• Lecturer.</li> <li>• Visiting Professor.</li> <li>• Adjunct Professor.</li> </ul>
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**PERS.3** Please list any Co-Principal Investigator(s):

<p>This page uses a <b>FIND PEOPLE</b> button to add personnel to your research study. If you cannot find someone from UNT you wish to add, they may not have requested Cayuse access.  <a href="#">Please follow this link for information on how to request access to Cayuse</a></p>	<p>In order to serve as Co-PI, you must be a full-time faculty staff member who is PI eligible. A person holding any of the following academic ranks can serve as a Lead PI or Principal Investigator (Co-PI):</p> <ul style="list-style-type: none"> <li>• Professor.</li> <li>• Associate Professor.</li> <li>• Assistant Professor.</li> <li>• Librarian.</li> <li>• Associate Librarian.</li> <li>• Research Professor.</li> <li>• Research Associate Professor.</li> <li>• Research Assistant Professor.</li> <li>• Research Scientist IV.</li> <li>• Research Scientist III.</li> <li>• Research Scientist II.</li> </ul> <p>Others may request approval to serve as a Lead PI or Principal Investigator (Co-PI). For persons with the following job titles, Lead PI or Principal Investigator status may be requested. <b>In order to be approved, a letter of support from your department chair/leadership must be provided:</b></p> <ul style="list-style-type: none"> <li>• Assistant Librarian.</li> <li>• Postdoctoral Research Associate.</li> <li>• Research Scientist I.</li> <li>• Director.</li> <li>• Lecturer.</li> <li>• Visiting Professor.</li> <li>• Adjunct Professor.</li> </ul>
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**PERS.4** Please list any Student Investigators:

<p>This page uses a <b>FIND PEOPLE</b> button to add personnel to your research study. If you cannot find someone from UNT you wish to add, they may not have requested Cayuse access.  <a href="#">Please follow this link for information on how to request access to Cayuse</a></p>	<p>Any student(s) will be listed here.</p>
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**PERS.5** Please list Key Personnel:

<p>Please list all key personnel (including anyone unaffiliated with UNT) Please list all key personnel (including anyone unaffiliated with UNT). If any Key Personnel are not found in the <b>FIND PEOPLE</b> button above, please list them here:</p>	<p>Any unaffiliated researcher(s) will be listed here.</p>
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**PERS.6** Please choose the Primary Contact for this study.

<p>This may be the same as the PI or Co-PI. If this is a student-led project, it may be a student.</p>	<p>The Primary Contact is the person who will primarily be in touch with the IRB regarding this submission. It may be any member of the research team affiliated with UNT</p>
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**PERS.7** Have all investigators and key personnel completed the required IRB human subjects online training?

<p>*Please attach a copy of all training certifications.</p> <p><input type="checkbox"/> Yes Please attach a copy of all training certifications. CITI certificates within three months of the expiration period are required to be renewed before approval.</p> <p><input type="checkbox"/> No Please complete your IRB human subjects training by following this link: <a href="#">IRB CITI Training and Education</a> Once training is complete, please change this answer to Yes (above), and attach a copy of your training certificate above.</p>	<p>Must answer 'yes' and provide training for each person listed in the Personnel section.</p> <p>Please read more about required trainings by following this link: <a href="https://research.unt.edu/research-services/research-integrity-and-compliance/human-subjects-irb/training-and-education">https://research.unt.edu/research-services/research-integrity-and-compliance/human-subjects-irb/training-and-education</a></p> <p>Training must be completed in the last three years. Everyone on study must have training completed.</p> <ul style="list-style-type: none"> <li>• If you are engaged in Social Behavioral Research the course requirement is "<b>Social &amp; Behavioral Research Investigators.</b>"</li> <li>• If you are engaged in Clinical/Biomedical Research, the course requirement is "<b>Biomedical Research.</b>"</li> <li>• All key study personnel (PI, Co-PI, and Study Coordinators) that are working on clinical trials must take the "<b>Good Clinical Practice (GCP)</b>" training modules.</li> <li>• For studies funded by the National Science Foundation (NSF), all key study personnel are required to take the "<b>UNT Responsible Conduct of Research (RCR) Basic</b>" training in the CITI program.</li> </ul>
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PERS.8 Will you be working with persons outside of UNT? In other words, do you have an external or unaffiliated Co-PI?

<p>External or unaffiliated persons are also required to submit a completed CITI training certification.</p> <p><input type="checkbox"/> Yes</p> <p>Please provide names, affiliations, and roles in the study. Please also include whether or not the non-UNT personnel will have access to identifiable data. See the (?) for more details ==&gt;</p> <p>If the outside researcher is unaffiliated with an IRB, please upload the Unaffiliated Investigator Agreement here:</p> <p><a href="#">Download the Unaffiliated Investigator Agreement</a></p> <p>ATTACH</p> <p><input type="checkbox"/> No</p>	<p>External investigators <b>relying on UNTIRB's</b> review need to upload a CITI training as described above.</p> <p>External investigators <b>with their own IRB approval</b> do not need to upload training.</p> <p>Unaffiliated Investigators need to upload a CITI training as described above.</p> <p>Per the Federal definition of Human Subjects Research, personnel who are not participant facing and have no access to any identifiable data are not considered to be engaged in research.</p> <p>Personnel who are not engaged in research do not need to be listed on this Personnel page.</p>
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## Section 1- Research Focus & Concepts

Research, for IRB purposes, is defined as a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

### 1.1 Describe the purpose of the study.

<p>In no more than a half a page, briefly state the purpose of your study in lay language - (simple everyday terms that someone who is not an expert in the field can understand), including the research question(s) you intend to answer.</p> <p>A brief summary of what you write here should be included in the informed consent form.</p>	<p>Explain the rationale and impetus for your research project. Provide enough detail such that: a) the IRB member(s) reviewing your protocol will understand your research plan and b) it supports a judgment of the risks and benefits in order to approve the use of the research participants.</p>
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### 1.2 Previous Research

<p>In no more than half a page, summarize previous research leading to the formulation of this study, including any past or current research conducted by the Investigator that leads directly to the formulation of this study (including citations and references.)</p>	<p>What literature is related to your research? On what are you basing your own work, pertaining to the use of human subjects? What are you doing that builds on existing research findings/best practices? What work has come before and what have you learned from it to inform your own methods and questions? Provide full citations (APA or MLA reference styles are preferred).</p>
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## Section 2- Methods

It is important that the procedures to be applied-some might call these treatments - to the human subjects are thoroughly explained and outlined. Those who will review and approve your study must fully understand what will take place during its conduct. Once approved, it is necessary that the procedures be carried out in the way they are officially described in this protocol.

### 2.1 Summarize the overall design of your proposed study.

<p>Please use lay language.</p>	<p>What kind of quantitative, qualitative, or mixed design are you using, for example, experimental randomized treatment, correlation, quasi-experimental, case study, etc.? What are the independent variables, interventions, treatments, etc.?</p>
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### 2.2 Will you be testing a food product on participants or providing a nutritional supplement to participants as part of the study?

<p><input type="checkbox"/> Yes Please provide detailed information on the food product and/or the nutritional supplement. e.g. brand, administering schedule, dosage, contact person for adverse effects, possible adverse effects, etc. <input type="checkbox"/> No</p>	
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### 2.3 Provide a step-by step outline of the activities included in this study.

<p><i>What events will occur and in what order? How will the information about the study be presented to the participants?</i></p> <p><b><u>Please use a numbered list if possible.</u></b></p>	<p>What events will occur and in what order? How will the information about the study be presented to the participants? Please describe the steps so that the IRB reviewer will understand your research plan.</p> <p>This can be shown in a bulleted or numbered list of events in the order as they occur.</p>
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## Section 3- Subjects & Recruitment

The terms subjects and participants are often interchangeable. A human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information. (Dept. of Health and Human Services, 45CFR46)

### 3.1 Recruitment of Participants.

<p>Describe the <b>MAXIMUM</b> projected number of subjects. If reviewing existing records, please list the total number of records.</p>	<p>Please provide a hard, total number (no estimates). Suggested text: "In total, no more than [XXX] participants will be enrolled in this study," (provide maximum number).</p> <p>It is acceptable to have a range, but it must be a close approximation. For projects with surveys (e.g., electronic, phone, written, door-to-door canvassing), indicate the number to be recruited, the anticipated response rate, and thus the estimated final number of actual participants. Note: The number provided in this section will be the maximum number of participants that can be recruited.</p>
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### 3.2 Describe the population from which subjects will be recruited (including gender, racial/ethnic composition, and age range).

<p>For example: "All participants will be 18 years of age or older. Subjects will not be excluded based on their race, gender, or ethnic composition." Otherwise, please state the specific demographics of the population you plan to use as subjects.</p>	<p>Must comment on gender, racial/ethnic composition and age range.</p>
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### 3.3 Describe how you will recruit subjects (face-to-face, e-mail, flyer, classroom announcement, etc.)

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### 3.4 Describe where recruitment of subjects will take place.

	<p>Requirements differ for methods of recruitment: As the risk of potential coercion rises, so too does the scrutiny level of the permission required. Passive methods – flyers/emails/social media posts or similar require only minimal permission [explanation as to what that is] Active/in person methods – require a formal letter of approval from a person with the authority to grant such.</p> <p>If recruitment will take place at a private entity (business, school,</p>
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	<p>social media group), an approval letter must be attached in this section.</p> <p>If researchers plan to post in a social media group (ex: Facebook group), a letter of approval from the group’s administrator must be uploaded. This letter of approval can be a screenshot from a conversation with the Facebook group administrator.</p> <p>Any email distribution lists need permission from the person who is responsible for the distribution list.</p> <p>If you want to send a blanket email to all students on campus, you need permission from the registrar’s office. Student Emails may only be used if PI’s have prior access to List servs with the desired emails on them. No emails may be requested from the Registrar’s Office.</p>
<p><b>ATTACH</b> If you are recruiting from a business, office, or school, please attach a consent letter from all locations on their company letterhead.</p>	<p>Permission letters as are required to be uploaded as for expedited and full board studies because of the elevated level of risk associated with this review level.</p>
<p>I have permission from all locations stated above to conduct recruitment for this research protocol and can produce them if required by the IRB.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

3.5 Have you attached a copy of all recruitment materials such as flyers, e-mails, scripts for classroom announcements, e-mails, and social media posts?

<p><a href="#">UNTIRB recommended recruitment templates</a> See the (?) for more details - especially about compensation amounts ==&gt;</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>3.5.2 If you are not submitting any recruitment material, please explain why. For example - the study involves the review of existing records and does not include direct or indirect recruitment.</p>	<p>UNT IRB has a list of required elements to be included in a recruitment message in order to fully inform a prospective participant about the research they are being asked to do:</p> <p>Please ensure the recruitment material includes the following:</p> <ul style="list-style-type: none"> <li>• "University of North Texas"</li> <li>• Name of Department</li> <li>• The word "research"</li> <li>• Official title of study</li> <li>• Location of research (if online, use, "online")</li> <li>• Inclusion criteria</li> <li>• Purpose of study</li> <li>• Study procedures and time requirement.</li> <li>• Compensation (If no compensation: "You will not receive compensation for participation.")</li> <li>• PI name and contact information.</li> </ul> <p>The UNT IRB has stated that a compensation amount of \$100 and below may be listed on recruitment material.</p>
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	To avoid undue influence, compensation above \$100 may be described as follows: "You will receive compensation for participation"
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### 3.6 Vulnerable populations

Vulnerable populations will require an Expedited or Full Board review application.

When a subject has limitations, is coerced or manipulated, there is a loss of capability to volunteer, and the subject may be vulnerable. According to regulations, vulnerable subjects include prisoners, pregnant women, minors and fetuses.

The IRB considers other kinds of vulnerability, for example, the possibility that bosses can coerce at the workplace and teachers can manipulate in the classroom. Research conducted with regulated vulnerable subjects requires demonstration of your training and experience with that specific population.

<p>3.6.1 If any boxes are checked, describe any special precautions to be taken in your study due to the inclusion of these populations.</p> <p><input type="checkbox"/> Children Children in most circumstances are those less than 18 years of age. Research with children involving no greater than minimal risk requires the permission of one parent and the assent of the child (45 CFR 46.404). Please note: Research involving minors is typically subject to full IRB review.</p> <p><input type="checkbox"/> Prisoners Please note: Research involving prisoners is typically subject to full IRB review.</p> <p><input type="checkbox"/> Mentally Impaired Please note: Research involving mentally impaired is typically subject to full IRB review.</p> <p><input type="checkbox"/> There are no vulnerable populations in this protocol.</p>	<p>If any vulnerable populations are checked, describe any special precautions to be taken in your study due to the inclusion of these populations.</p> <p>Any study working with vulnerable populations will not be considered for Exempt level review.</p>
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### 3.7 Location of the Study

<p>Identify all locations where the study will be conducted.</p>	<p>Will you be conducting any experiments in a lab or classroom or collecting data in the field? The IRB needs evidence that you are permitted to conduct the research in other venues for the protection of you, your subjects, and institutions. For example, a signed letter or email authorizing a study at your work or in a business, or from a school principal or school board, or to use the UNT student health center will be required for protocol approval. Provide information about the human subjects procedures that apply for your international studies (see the <a href="#">UNT IRB Policies and Procedures page</a>).</p>
<p>3.7.2 If you are conducting your research study at a business, office, or school, please</p>	<p>Permission letters as are required to be uploaded as for Expedited and Full Board studies because of the elevated level of</p>

<p>attach a consent letter from all locations on their company letterhead. <b>ATTACH.</b></p>	<p>risk associated with this review level.</p>
<p>I have permission from all locations stated above to conduct recruitment for this research protocol and can produce them if required by the IRB.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>This is specifically for Exempt level studies – only appears when Exempt level review is selected in question CI.7</p>

## Section 4- Data Collection

Data collection methodologies include, but are not limited to surveys, interviews, focus groups, observational research in public schools, physiological sensors, weight scales, and extracting information from existing data sets.

Data includes: the information (responses) on survey sheets and questionnaires, biological samples, audio and video tapes, and interview questions. If performing audio recordings, please mention who will be responsible for transcribing the audio data. If you intend on using a third-party transcription company, please provide a copy of that company's non-disclosure agreement. In addition, if audio data is not de-identified prior to transcription by a third-party company, or anyone other than the investigators or key personnel mentioned on the application, please ensure they provide a copy of their NIH training for human subject's certification. Audio recordings should be verified by the subjects before any dissemination of data occurs.

If you are using audi/video recording, please mention how you plan to keep the subject's anonymity.

All data collected needs to be stored on the UNT campus with the Supervising Investigator for a minimum of three years past the end of the study.

### 4.1 Please select the methods you will use to collect data.

<p>Please note: If you plan to conduct a study using biologics/biological samples, you will be referred to our Institutional Biosafety Committee (IBC) to submit a protocol. You must receive IBC approval before IRB approval will be issued.</p> <p><input type="checkbox"/> <b>Interviews</b>                  4.1.1 Please explain how this will be done, and how the interviews will be documented.                  4.1.1.1 Please attach a list of the interview questions.                  ATTACH</p> <p><input type="checkbox"/> <b>Paper Survey/Questionnaire</b>                  4.1.2 Please attach a copy of all paper surveys and questionnaires.                  ATTACH</p> <p><input type="checkbox"/> <b>Internet Surveys/Questionnaires</b>                  Please attach a copy of all internet surveys and questionnaires.                  4.1.3 The survey upload should be an exported PDF representation of the online survey showing the Informed Consent Notice at the beginning, followed by the survey questions for IRB review. <b>See the (?) for more details ==&gt;</b>                  ATTACH</p> <p><input type="checkbox"/> <b>Focus Groups</b>                  4.1.4 Please explain how this will be done, and how the Focus Groups will be documented.                  Please attach all materials related to the Focus Group.</p>	<p>Describe <u>in detail</u> all procedures to be done with human subjects. <u>What</u> types of test(s) will you perform on or with the subjects? <u>How</u> will you carry them out?</p> <p><b>Interviews:</b>                  Please attach a list of interview questions. If the interview is unstructured, please attach a list of the original questions that will be asked.                  Please answer: How long will the interviews take place? Where will they take place? What information from the interview will be documented?  <b>Paper Surveys/Questionnaire:</b>                  Please upload the questions exactly how the participants(s) will see them.</p> <p><b>Internet Surveys/Questionnaires:</b>                  Attach a PDF copy of the questions with the consent form as it appears in section 8 as the first page.</p> <p><b>Focus Group:</b>                  Please attach all materials that will be distributed. Include language specific to focus groups in the consent document (Upload in Section 8).</p> <p><b>Review of Existing Records:</b>                  Please explain how the data will be obtained. If the data has restricted access (ex. federal data</p>
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<p>ATTACH</p> <p><input type="checkbox"/> <b>Review of Existing Records</b></p> <p>4.1.5 Please describe below the records you plan to review. Have these records been de-identified? If obtaining from an outside source, please provide approval from the outside source stating you can review these records.</p> <p>4.1.5.1 Please upload any approvals you have obtained below. Alternatively, if required, please upload the list of datapoints to be reviewed below. NOTE: UNTIRB does NOT require raw data to be uploaded.</p> <p>ATTACH</p> <p><input type="checkbox"/> <b>Observation</b></p> <p>4.1.6 Please explain the situation in which you intend to observe people. An observation is generally either an exempt observation or an observation that requires consent. An exempt observation is a public observation where the researcher is watching the interactions of people in a public space. A private space is any area that is considered a private residence or private workspace and where the participant has an expectation of privacy.</p> <p><input type="checkbox"/> <b>Public Observation</b></p> <p>4.1.6.1 e.g. in a public setting like a park or on the street. For consent considerations, <b>please click the (?) to the right ==&gt;</b></p> <p><input type="checkbox"/> <b>Private Observation</b></p> <p>4.1.6.2 This is anywhere where there is an expectation of privacy - in a person's home, place of business, or classroom. For consent considerations, <b>please click the (?) to the right ==&gt;</b></p> <p><input type="checkbox"/> <b>Exercise Protocol</b></p> <p>4.1.7 Please describe in detail what physical activities the subjects will be engaged in, the time duration, and any safety precautions that will be put in place.</p> <p><input type="checkbox"/> <b>Other</b></p> <p>4.1.8 Please explain.</p> <p>4.1.8.1 In the space below, please upload any relevant attachments that do not directly correspond to the categories above. E.g. reference/guidance documents, class assignments, gameplay screenshots, instruction books/manuals to be followed.</p> <p>ATTACH</p>	<p>repositories) please clarify. Please describe if the data will deidentified or identifiable. Please provide a description of what the data set contains.</p> <p><b>Observation:</b> You are not required to obtain consent from the people you observe unless one of the following occurs:</p> <ul style="list-style-type: none"> <li>• Observation changes from a public sphere to a private sphere (i.e. private residence, office, classroom).</li> <li>• Observation requires that private information or identifying information be collected about specific individuals.</li> <li>• Those observed are not children.</li> <li>• The observations could not reasonably place the subject at risk (legal, financial, employment, reputation) if they became known outside the research.</li> </ul> <ol style="list-style-type: none"> <li>1. Participant observation may require a Letter of Permission from a “gatekeeper” of the institution/organization involved (e.g., the Director, Owner, and/or Manager.)</li> <li>2. If it is not feasible to present each individual with a written consent form, think about how to make people aware of the research and give them the opportunity to opt out of participation (such as by using a Study Information Sheet.) If they opt out, do not include them in your notes or project.</li> <li>3. Use written consent unless you have a reason to use oral consent instead. In the case of oral consent, you still will need a written document to provide to the participant – and guide the consent process.</li> </ol> <p><b>Other:</b> Anything else not listed here. This includes documents relevant to the study provided to participants for their reference.</p> <p><b>Exercise Protocol:</b> Please note this is physical exercise (ex: running on a treadmill).</p>
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<p><input type="checkbox"/> <b>DXA or Radiographic Imaging</b></p> <p>4.1.9 Please ensure the required IRB guidelines have been added to your Informed Consent document (i.e., urine testing of women of childbearing age, side effects of radiation, etc.)</p> <p>4.1.9.2 Please upload your current DXA/Radiographic Imaging Certificate.</p> <p>ATTACH</p>	<p><b>DXA or Radiographic Imaging:</b> Requires radiation safety approval from risk management. Usually in the form of the certification to use the machine.</p>
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4.2 Does your study collect or analyze any biological samples?

<p>(For example: blood, urine, tissue, saliva, etc.)</p> <p><input type="checkbox"/> Yes</p> <p>4.2.1 Please list the biological samples that will be collected or analyzed. Please also explain the volume, frequency, and techniques of collection.</p> <p>4.2.2 How will the biological samples be obtained?</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Collected by a member of the research team.</li> <li><input type="checkbox"/> Collected by the Subject</li> <li><input type="checkbox"/> From an existing tissue bank</li> <li><input type="checkbox"/> Other (please explain)</li> </ul> <p>4.2.3 Will the biological samples be processed in the lab at UNT?</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Yes</li> <li><input type="checkbox"/> No</li> </ul> <p>4.2.4 Please describe the plan for storage of biological samples collected or obtained. Describe how long the samples will be stored, where they will be stored and if/how they will be disposed of</p> <p>4.2.5 Please upload a copy of the IBC approval, if applicable</p> <p>ATTACH</p> <p><input type="checkbox"/> No</p>	<p>If yes, risk management approval is required. Any study working with biological samples will not be considered for Exempt level review.</p>
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4.3 Will your study involve audio-recording or video-recording the participants?

<p><input type="checkbox"/> Yes</p> <p>For audio: Please mention who will be transcribing audio data. For pseudonyms, please mention the criteria that will be used to ensure subject’s anonymity. If a third party-company is doing transcription, please submit a copy of their non-disclosure agreement.</p> <p>For video: Please mention how you plan to keep subject’s anonymity (i.e., will subject’s face be blurred?)</p> <p>For all recordings, please verify that subject approval will be obtained before any dissemination of data.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Audio only</li> <li><input type="checkbox"/> Video only</li> </ul>	<p>Any study working with Audio/Video recordings in which the participants will be identifiable will not be considered for Exempt level review. E.g. those studies where the audio/video is an integral part of the study and will be used in the publications/presentations.</p> <p>Audio and video recordings used in interview and focus group studies <b>to ensure accuracy of transcription only</b> and will not be used in publications or presentations are still eligible for Exempt review.</p>
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<input type="checkbox"/> Audio & Video <input type="checkbox"/> No	
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4.4 Please select below all use cases for third-party online websites:

<p>Note: the Google family of products is not approved by UNT IT services for use in conjunction with UNT Research.</p> <p>All third-party websites are subject to privacy policy review in order to assess their use of participant data and may be rejected by the UNTIRB.</p> <p><input type="checkbox"/> Will you be using any third-party online websites <b>to collect data from participants?</b></p> <p>Please list the websites below and explain the purpose for which participants will be directed to those.              These include but are not limited to: Qualtrics, Survey Monkey, Microsoft Forms, Zoom/Teams, etc.</p> <p><input type="checkbox"/> Will you <b>upload data to</b> any third-party online websites for analysis?</p> <p>Please list the websites below and explain the purpose(s) for which you intend to use them.              These include but are not limited to qualitative data analysis or transcription websites such as NVivo or Rev.com.</p> <p><input type="checkbox"/> Will you be directing participants to any third-party online websites <b>for any other purpose?</b></p> <p>Please list the websites below and explain the purpose for which participants will be directed there.              This includes, but is not limited to recruitment, direction to a resource for research purposes, etc.</p> <p><input type="checkbox"/> None</p>	
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4.5 Will you be gathering information from the subject's medical records?

<p><input type="checkbox"/> Yes              Explain compliance with the HIPAA privacy rule (Health Insurance Portability and Accountability Act) and disclosure of protected health information (PHI).</p> <p><input type="checkbox"/> No</p>	<p>If yes, HIPAA language needs to be in the consent form. HIPAA consent template can be found here: <a href="https://research.unt.edu/research-services/research-integrity-and-compliance/human-subjects-irb/irb-forms-and-templates">https://research.unt.edu/research-services/research-integrity-and-compliance/human-subjects-irb/irb-forms-and-templates</a></p> <p>The HIPAA Privacy Rule regulations [45 CFR 164.514(b)] list specific elements that are considered to be personal identifiers. These include: name and initials; street address, city, county, precinct, zip code, or equivalent geocodes; elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death); elements of date including year for persons 90 or older; telephone and/or fax number; e-mail</p>
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	address; social security number; medical record or health plan identification number; account number; certificate and license number; vehicle identifier and serial number including license plate number; device identifier and serial number; web address (URL), internet IP address; biometric identifier including finger and voice print, full face photographic image and comparable image; other unique identifying number, characteristic, or code.
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## Section 5- Data Security

### 5.1 Is the study:

<p>Before deciding whether your study is considered confidential or anonymous, <b>please see the ('?') for more details ==&gt;</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Confidential</li> <li><input type="checkbox"/> Anonymous</li> </ul> <p>5.1.1 A truly anonymous study meeting the IRB definition is very rare. Please describe below the steps you intend to take to ensure the study is truly anonymous.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> None/Neither</li> </ul> <p>5.1.2 If you are not providing subject privacy or anonymity, please also include that in the Confidentiality section of your informed consent document.</p>	<p>A <b>strictly anonymous</b> study design is one in which it is impossible to trace data or information back to the research subject from whom it was obtained. In other words, the data <b>cannot</b> be identified to any particular research participant, not even by the researcher. There is total separation. No study design that involves the creation of a code linking the subject's identity to a pseudonym or a number can be termed an anonymous study, as the identity of the subject can be traced to the data. Additionally, when a written consent form is collected, this consent form must be separated from the data that the subject provides. The PI (principal investigator) needs to describe in the protocol how this will be accomplished.</p> <p><b>Confidential</b> research participation means that the data from the research subject(s) <b>can</b> potentially be identified or linked to a particular individual. Thus, <b>any</b> data collected face-to-face (consumer survey, focus groups, standing in front of a classroom, etc.) is automatically considered in the category of being confidential as opposed to anonymous. This is true even when the researcher assigns a coding number to the subject and this number cannot be traced back to the subject because the researcher him/herself knows who provided the data.</p>
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### 5.2 Will Personally Identifiable Information (PII) be collected/used?

<p>This refers to <b>ANY</b> PII used in recruitment or any other phase of the project, including data gathered from participants. <b>See the ('?') for more details ==&gt;</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Yes</li> </ul> <p>5.2.1 Please check all PII that you are either using to communicate with participants OR are gathering as part of data collection:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Name</li> <li><input type="checkbox"/> Address (all geographic subdivisions smaller than the state, including street address, city, county, and zip code).</li> <li><input type="checkbox"/> Email address.</li> <li><input type="checkbox"/> Telephone numbers.</li> </ul>	<p>Keep in mind that some demographic data are considered to be identifiers. If you are collecting data online, know that an IP address is considered to be an identifier. <a href="#">MORE INFORMATION</a></p> <p>If yes, please provide information on how identifiers will be removed or coded to protect participant's confidentiality.</p>
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<ul style="list-style-type: none"> <li><input type="checkbox"/> Internet Protocol (IP) Address</li> <li><input type="checkbox"/> Finger or voice print</li> <li><input type="checkbox"/> Photographic image - Photographic images are not limited to images of the face.</li> <li><input type="checkbox"/> Social Security Number</li> <li><input type="checkbox"/> Fax number</li> <li><input type="checkbox"/> Medical record number</li> <li><input type="checkbox"/> Health plan beneficiary number</li> <li><input type="checkbox"/> Account number(s)</li> <li><input type="checkbox"/> Certificate or license number</li> <li><input type="checkbox"/> Any vehicle or other device serial number.</li> <li><input type="checkbox"/> Web URL</li> <li><input type="checkbox"/> Any other characteristic that could uniquely identify the individual.</li> <li><input type="checkbox"/> Other, not listed above (please specify).</li> </ul> <p>5.2.1.1</p> <p><input type="checkbox"/> No</p>	
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5.3 Who will have access to the data (and/or biological samples)?

<ul style="list-style-type: none"> <li><input type="checkbox"/> Members of the research team (e.g. those mentioned in the Personnel Section).</li> <li><input type="checkbox"/> Others - Please list below.</li> </ul> <p>5.3.1 Please also specify if the data to be shared is considered identifiable or de-identified.</p>	<p>Please state who will have access to the data. Clarify if the data will be open access or stored and protected.</p>
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5.4 Will any data collected from the study be made available as open access?

<ul style="list-style-type: none"> <li><input type="checkbox"/> Yes             <ul style="list-style-type: none"> <li>5.4.1 If yes, please clarify how data will be made available as open access- For example, some funders and journals request that data be housed (kept, stored) at an approved site (e.g., clinicaltrials.gov), accessible to the public.</li> </ul> </li> <li><input type="checkbox"/> No</li> </ul>	
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5.5 How will the raw data be kept protected and secured?- See the ('?') for more details ==>

<ul style="list-style-type: none"> <li><input type="checkbox"/> SharePoint/OneDrive/Other UNT storage system.</li> <li><input type="checkbox"/> UNT System-issued laptop (not a personal one).</li> <li><input type="checkbox"/> Paper/Physical files stored in a locked cabinet on a UNT campus in the PI's office.</li> <li><input type="checkbox"/> Other (including international research). Please provide more details below.             <ul style="list-style-type: none"> <li>5.5.1 For international research please provide details of how the data will be kept secure while traveling.</li> </ul> </li> </ul>	<p>Data storage should be password protected and stored only on UNT-issued devices - For electronic data, approved UNT servers (OneDrive, SharePoint, Teams) are permitted. Please note, that additional electronic storage services/applications may need to be reviewed by IT security. Physical paper data should be stored in a locked cabinet on the UNT campus in the PI's office.</p> <p>Note: for UNT Dallas, UNT-D's issued devices and</p>
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	servers are appropriate.
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5.6 What will become of the data (and/or biological samples) at the end of the study?

<input type="checkbox"/> Data will be kept on the UNT campus in the PI's office/UNT server for a period of three years past the end of the study. <input type="checkbox"/> Other (Please explain below). 5.6.1	Will the data be returned, destroyed, archived, etc.?  Per federal regulations, all collected data is required to be kept on UNT campus for three years past the end of the study
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5.7 How will the data, results, and conclusions be utilized?

Do you plan to use any data in a presentation, publication, or something else? Will any data be used *only* internally, for example within an institutional department? <input type="checkbox"/> Presentation <input type="checkbox"/> Publication <input type="checkbox"/> Other (please explain) 5.7.1 <input type="checkbox"/> ONLY internally, for example within an institutional department (please explain). 5.7.2	Will the data be shared with any other researchers or funding agencies? Will these data appear in a published thesis or journal publication? This information, summarized, must be included in the consent form.  If true, state "Data will be reported in aggregate without identifiers."
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## Section 6- Potential Risks Potential Risks, Benefits, & Compensation

Definition of risk: A potential harm, discomfort, or inconvenience associated with your research that a reasonable volunteer would be likely to consider significant in deciding whether or not to participate. Risks include legal, social, emotional, or psychological issues, physical or biological hazards, revealing an identity, damage to reputation, exposure of behavior or medical character, illness, injury, side effects of applied or consumed products, revealing or a loss of private information, etc. Risk comes at various orders of magnitude, ranging from mere inconvenience to perceptible bodily pain.

### 6.1 What are the risks? Describe any potential harm, discomfort, or inconvenience, however minimal, as you would explain them to the subjects.

<p>If foreseeable risks involve the possibility that the subject may need counseling after the completion of the study, please include a list of 24-hour resources (including contact information) in the Possible Risks/Discomforts section of the informed consent document.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Study meets the <b>Exempt</b> definition for <b>less than</b> minimal risk.</li> <li><input type="checkbox"/> Study meets the <b>Expedited</b> definition for <b>no more than</b> minimal risk.</li> </ul> <p>6.1.1 Please explain the additional risks posed by an Expedited review-level study.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Confidentiality. (loss of confidentiality is a risk for all studies).</li> <li><input type="checkbox"/> Other (Please explain).</li> </ul> <p>6.1.2</p>	<p><b>Expedited</b></p> <p>To qualify for review at an Expedited level, the study must be no more than minimal risk and fit in one of the federally designated <a href="#">Expedited review</a> categories (<a href="#">45CFR46.110</a> and <a href="#">21 CFR 56.110</a>).</p> <ul style="list-style-type: none"> <li>• Analyses of voice recordings.</li> <li>• Studies of existing pathological specimens with patient identifiers.</li> <li>• Collection of blood samples, up to 550ml, from healthy, non-pregnant adults who weigh at least 110 pounds.</li> <li>• Collection of data using physical sensors that are applied either to the surface of the body or at a distance with minimal risk.</li> <li>• Research on characteristics, behavior, research surveys, interviews, focus groups, program evaluations, or quality assurance methods that do not fall into exempt categories.</li> </ul> <p><b>Exempt</b></p> <p>To qualify for review at the Exempt level, the research must not be greater than minimal risk and must fall into one or more of the Exempt categories (45CFR46.104). Exempt reviews are conducted typically by only one reviewer within the Research Integrity and Compliance Office. Typically, no annual renewal is required to be submitted. Modifications must be submitted.</p> <ul style="list-style-type: none"> <li>• Evaluating the use of accepted or revised standardized tests.</li> <li>• A program evaluation of pharmacy continuing education.</li> <li>• Interviewing managers about a management style or best practice.</li> <li>• Conducting a focus group about an experience or</li> </ul>
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	<p>an opinion of a community program.</p> <ul style="list-style-type: none"> <li>Solving puzzles under various noise conditions.</li> </ul> <p><b>Full Board</b> More than minimal risk studies, as determined by the IRB Chair. Also, any human subjects research study that does not fit into one of the federal categories for Exempt or Expedited.</p>
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6.2 Describe your procedures for protecting against or minimizing the potential risks stated above.

<p>For each of the risks indicated above, please list a countermeasure to minimize the risk to participant.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Data will be stored in password-protected UNT devices/in UNT-locked offices and made accessible only to members of the research team. (to mitigate potential for loss of confidentiality)</li> <li><input type="checkbox"/> Study meets the Expedited definition for no more than minimal risk.</li> </ul> <p>6.2.1 Please explain the additional countermeasures to risks posed by an Expedited review-level study.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Other (please explain).</li> </ul> <p>6.2.2</p>	<p>For every risk stated above, there should be a procedure listed to minimize that risk.</p>
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6.3 These risks are determined as reasonable in relation to the anticipated benefits:

<ul style="list-style-type: none"> <li><input type="radio"/> Yes</li> <li><input type="radio"/> No</li> </ul>	
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6.4 Describe the anticipated benefits to subjects or others (including your field of study).

<p>Compensation does not count as a benefit and should not be included.</p>	<p>Benefits should be both to the subject and the field of study as often there are no direct benefits to the subject at UNT. Compensation does not count as a benefit and should not be included.</p>
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6.5 Will you utilize any of the following for the study's potential risks?

<p>Check all that apply.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Debriefing Statement 6.5.1 Please explain how the debriefing statement will be provided to the participant. 6.5.1.1 Please upload your debriefing statement here: For a list of required elements for debriefing statements, See the ('?') for more details ==&gt;</li> <li><input type="checkbox"/> Counseling and Psychological Services/help resources. 6.5.2 Please explain how the counseling resources will be provided to the participant. For a list of suggested for counseling resources, See the ('?') for</li> </ul>	<p>The Debriefing Form should include the following:  (Remove the deception elements if deception is not part of the study):</p> <ol style="list-style-type: none"> <li>Study title.</li> <li>Researcher’s name and contact information, if applicable, for follow-up questions.</li> <li>Thank participants for taking the time to participate in the study.</li> <li>Explain what was being studied (i.e., purpose,</li> </ol>
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<p>more details ==&gt;</p> <p><input type="checkbox"/> Adverse event protocol (medical emergency services contact).</p> <p>6.5.3 Please explain how the adverse event protocol will be carried out.</p> <p><input type="checkbox"/> None</p>	<p>hypothesis, aim). Use lay terms and avoid use of jargon.</p> <ol style="list-style-type: none"> <li>5. Explain how participants were deceived.</li> <li>6. Explain why deception was necessary in order to carry out the research.</li> <li>7. Explain how the results of the deception will be evaluated.</li> <li>8. If the study involves use of audio or videotaping an individual participant, give the participant an opportunity to withdraw his/her consent for use of the tapes and, potentially, withdraw from the study all together, after the true purpose of the study is revealed. The IRB suggests that participants be given at least 48 hours to make this decision and provide contact information for whom participants should contact regarding their withdrawal from the study. This option must be given to participants even if they were video or audiotaped during a focus group or during an experiment involving other participants. If a participant decides to withdraw, the PI must use video editing tools to make an individual who withdraws unidentifiable. If tools are not available, the PI cannot use the video or audiotape.</li> <li>9. Provide participants an opportunity to withdraw their consent to participate or to withdraw their data from the study.</li> <li>10. If applicable, explain anticipated or observed results so far.</li> <li>11. Offer to provide them with the study results.</li> <li>12. Provide references/website for further reading on the topic.</li> <li>13. Provide a list of resources participants can seek if they become distressed after the study.</li> </ol> <p><b>Please select the most appropriate resource based on your participant population and your study. If the population studied are not all UNT staff and students, please provide a resource outside the UNT Campus resources.</b></p> <p>Suggested counseling resources:</p> <ul style="list-style-type: none"> <li>• Denton County MHMR crisis hotline at 1-800-762-0157.</li> <li>• UNT Mental Health Emergency line at 940-565-2741.</li> <li>• Family Violence Shelter of Denton County Crisis</li> </ul>
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	<p>Line at 940-382-7273.</p> <ul style="list-style-type: none"> <li>• National Suicide and Crisis Lifeline at 988.</li> <li>• UNT Survivor Advocate for students effected by Violence or Sexual Assault at 940-565-2648.</li> </ul>
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6.6 Will you be providing compensation to the participants?

<p><input type="checkbox"/> No.  <input type="checkbox"/> Yes.</p> <p>6.6.1 Please describe the type of compensation that will be offered. See the ('?') for the required compensation information ==&gt;</p>	<p>Please state “No” if there will be no compensation.</p> <ul style="list-style-type: none"> <li>• Anything a subject will receive for participation is compensation. (food, money, extra credit etc.).</li> <li>• If the item is food or a consumable good, please provide an estimated monetary value. (EX: “Lunch is provided for subjects valued at \$15 a meal.”)</li> <li>• The UNT IRB has stated that a compensation amount of \$100 and below may be listed on recruitment material.</li> <li>• To avoid undue influence, compensation above \$100 may be described as follows: "You will receive compensation for participation."</li> </ul> <p>All information about compensation <b>MUST</b> be stated on the informed consent.</p> <p><b>Required compensation information:</b></p> <ol style="list-style-type: none"> <li>1. Who will it be offered to?</li> <li>2. What form will the compensation take? (Note UNTIRB does not allow for cash to be provided as compensation)</li> <li>3. How much will there be?</li> <li>4. When will it be provided to participants, and how?</li> <li>5. Will compensation be pro-rated to the level of participation?</li> <li>6. If extra credit for a course is offered, an alternative non-research activity with equivalent time and effort must also be offered.</li> </ol>
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## Section 7- Affiliations

These questions ask about how you are related to the institution and subjects where the research project is to be conducted. As examples: you are a teacher using your students in a classroom setting as your subjects, or you work for the company where a marketing survey is to be conducted, or you have a financial interest in a product being tested. Each of these examples presents an element of risk. IRB reviewers will evaluate whether these risks are reasonable and whether they are sufficiently controlled, minimized, or eliminated by your procedures.

### 7.1 Do you have any kind of pre-existing relationships with the subjects (participants), or institutions involved in conducting this study?

<p>Working at the place where the study is to be conducted may be seen as coercive to others. Consider the possibility that collection of data from either the participant or institution may be seen as a favor when asked to volunteer information. The IRB is interested in reading a statement from the PI(s) of the potential and it may be of no concern at all.</p> <p><input type="checkbox"/> Yes 7.1.1 Please explain.</p> <p><input type="checkbox"/> No</p>	<p>Examples: Teacher to Student, Colleague to Colleague, Boss to Subordinate etc.</p> <p>State any type of relationship that is related to the conduct of the study. If you work for an off-campus organization or entity and need to keep its identity confidential, note that here. See the following guidelines at the NIH website. <a href="https://toolkit.ncats.nih.gov/glossary/conflict-of...">https://toolkit.ncats.nih.gov/glossary/conflict-of...</a></p>
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### 7.2 As an investigator involved with the project, do you or any of your family members (e.g. spouse, child) have a financial or other self interest in this study?

<p><input type="checkbox"/> Yes 7.2.1 Please explain.</p> <p><input type="checkbox"/> No</p>	<p>For example: an MBA student may conduct a consumer survey about establishing a business (restaurant) she herself wants to open. In this case, there could be a need for disclosure of that fact in the informed consent form.</p>
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### 7.3 Though there may not be one, could there be the perception of a conflict of interest for either you, as the investigator, or for the subjects in this study?

<p><input type="checkbox"/> Yes 7.3.1 Please explain.</p> <p><input type="checkbox"/> No</p>	<p>If yes, please provide a management plan. <a href="#">NIH Conflict of interest definition</a></p>
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## Section 8- Informed Consent & Assent Form(s) (ICFs)

The Informed Consent Form (ICF) is how you as the PI convey the specific details of your research and the principles of human subjects' protection to your subjects: respect, beneficence, and justice. There are examples on the [IRB Forms and Templates page](#).

Please be sure to choose the correct version to use for your project -

- [Exempt Studies Informed Consent Template](#) - This template is to be used for **Exempt studies only**.

For **Expedited** or **Full Board** level studies, please choose one of the following:

- [Informed Consent Form - Adults](#) - The consent form used for most studies that require a signature.
- [Informed Consent and Assent Forms - Parents and Minors](#) - Parental consent/permission and child assent forms that are used for studies enrolling minors.
- [Informed Consent Form- With HIPAA Authorization](#) - A consent form used when medical information (HIPAA) will be collected.
- [Informed Consent Notice - Electronic Consent](#) - Consent form used for electronic surveys.

If in doubt consult the [regulatory definitions](#) in the help text in the '?' to the right, or contact the UNT IRB at [untirb@unt.edu](mailto:untirb@unt.edu)

To test your ICFs for appropriate reading levels, submit your ICF to this software: <http://www.readabilityformulas.com/flesch-grade-le...>

### 8.1 How will you obtain and document informed consent?

<p>See the (?) for more details ==&gt;</p>	<p>Please describe the interaction between the subject and researcher. Please be specific about exactly how you intend to obtain informed consent - Provide a step-by-step outline of the method of obtaining consent.</p> <p>What events will occur and in what order? How will the informed consent be sent to the participant, and how will they indicate their consent and return it?</p>
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### 8.2 Will there be recruitment of subjects who cannot themselves provide informed consent?

<p><input type="checkbox"/> Yes 8.2.1 How will informed consent be documented for this population? <input type="checkbox"/> No</p>	<p>For example, the ability of minors to assent could be dependent upon their age and/or their circumstance(s). Persons in vulnerable situations could be impaired in their ability to understand the study and be able to consent.</p> <p>Please be specific about exactly how you intend to document informed consent - Provide a step-by-step outline of the method of obtaining consent.</p> <p>What events will occur and in what order? How will the informed consent be sent to the participant, and</p>
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	how will they indicate their consent and return it?
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8.3 How will you obtain and document parental/guardian consent and child/minor/ward assent?

	<p>This will appear upon selecting Expedited/Full Board in question CI.7 also.</p> <p>Assent means a child's affirmative agreement to participate in research. (<a href="#">45 CFR 46.402(b)</a>).</p>
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8.4 Select the type of ICF you will utilize.

<p>Note that you should add the current IRB protocol number obtained when you created this protocol in Cayuse to your ICF(s) before you upload it to this site.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Informed Consent Form (paper version). This is the most typical means used in face-to-face explanations of a study to convey the ICF elements to potential subjects/participants. This form requires signatures from both the participant and the investigator.             <ul style="list-style-type: none"> <li>8.4.1 ATTACH</li> <li>8.4.2 Describe the subject group that will be consented utilizing a paper consent form. If the answer is all study subjects, please write "all subjects."</li> </ul> </li> <li><input type="checkbox"/> Informed Consent Notice (electronic/other). Fill this section out if you are obtaining verbal consent, or another type of consent that is not a handwritten signature.             <p><b><i>Also check this box for review of existing records where no consent is needed, and fill out the <u>Waiver/Alteration of Informed Consent</u> also.</i></b></p> <p>This version is commonly used with online surveys because the participants and investigators are not required to sign the document. Instead clicks/check boxes are used to indicate yes/I agree or no/I don't agree as a means to continue to the survey or exit the survey. A copy of this document still needs to be submitted to the IRB office for approval.</p> <ul style="list-style-type: none"> <li>8.4.4 ATTACH</li> <li>8.4.5 Describe the subject group that will be consented utilizing an electronic consent form. If the answer is all study subjects, please write "all subjects."</li> </ul> </li> </ul> <ul style="list-style-type: none"> <li><input type="checkbox"/> If obtaining Child/Minor/Ward Assent, please upload it here.</li> </ul> <p style="color: red;">Assent for Child Participation? Ages 13-17 - Children in this age range can assent by reading through the consent form provided to their parent.</p>	<p>A Waiver of Informed Consent is required if you are using the Informed Consent Notice- Electronic Consent form.</p> <p>Consent forms and templates can be found here:              UNT IRB Forms and Templates:  <a href="https://research.unt.edu/research-services/research-integrity-and-compliance/human-subjects-irb/irb-forms-and-templates">https://research.unt.edu/research-services/research-integrity-and-compliance/human-subjects-irb/irb-forms-and-templates</a></p> <p>Waiver of Consent should be when a 'wet' signature is not being obtained.</p> <p>This document is required to be written to an 8th grade reading level.              This can be checked on Microsoft word by the Seeking out the Flesch-Kincaid score which equates to grade reading level.</p> <p>On Word:              REVIEW → Editor → Insights → Document Stats → Flesch-Kincaid grade level.</p> <p>Assent means a child's affirmative agreement to participate in research. (<a href="#">45 CFR 46.402(b)</a>).</p> <p>The assent form should be age appropriate.</p>
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<p>Age Range 12 and Under - It is recommended that you create a simplified version of the parental consent. Where possible, allow the child to read it on their own, and/or verbally explain certain sections to make certain the child understands. For children ages 7 years and younger, it is highly recommended that the research team verbally explain the procedures in simple, clear language so they are certain the child understands.</p>	
<p>8.4.6 ATTACH</p> <p><input type="checkbox"/> <b>Waiver/Alteration of Informed Consent.</b> When obtaining consent is not practicable in order to conduct the research; see the federal regulations.</p>	
<p><a href="#">Request for Consent Alteration/Consent Waiver</a> - Required form if you are using the Informed Consent Notice- Electronic Consent form or deviating from a handwritten signature in any way.</p>	
<p>8.4.7 ATTACH</p> <p>8.4.8 Justify the need for a waiver. A justification is required and will be evaluated by the IRB member(s) doing the protocol review. "Convenience" is not a valid reason. An example is that it's impractical during medical research to obtain consent from someone unconscious. Please also list the study subjects that this waiver will apply to. If the answer is "all study subjects", please state that below.</p>	

8.5 Which study personnel will be involved in obtaining consent?

<p>Please understand that this makes such personnel engaged in research and only those listed in the Personnel Section of this protocol should be listed below. See the (?) for more details ==&gt;</p> <p>This list of researchers should also be included in the informed consent form, along with the PI.</p> <p><input type="checkbox"/> All research team members listed in the Personnel Section.</p> <p><input type="checkbox"/> Selected research team members.</p> <p><input type="checkbox"/> Other (Please explain below).</p>	<ol style="list-style-type: none"> <li>1. <b>Researcher:</b> Any individual performing various tasks related to the conduct of human subjects research activities, including but not limited to <b>obtaining informed consent</b> from subjects, <b>collecting and analyzing data, interacting with subjects,</b> and communicating with the IRB.</li> <li>2. The PI should <b>always</b> be listed on the informed consent, regardless of whether they are involved in obtaining consent.</li> <li>3. All other <i>participant facing</i> research team members should be listed both here and on the informed consent contact section.</li> </ol>
<p>8.5.2</p>	

8.6 Describe how you will maintain and secure the consent forms received from the subjects?

<p>Consent forms can be electronic or paper.</p> <p><input type="checkbox"/> SharePoint/OneDrive/Other UNT storage system.</p>	<ul style="list-style-type: none"> <li>• Where (the location) will they be kept? For how long/until when?</li> </ul>
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<ul style="list-style-type: none"> <li><input type="checkbox"/> UNT System-issued laptop (not a personal one).</li> <li><input type="checkbox"/> Paper/Physical files stored in a locked cabinet on a UNT campus in the PI's office.</li> <li><input type="checkbox"/> Other (including international research). Please provide more details below.             <ul style="list-style-type: none"> <li>8.6.1 For international research please provide details of how the data will be kept secure while traveling (documents should never be left unattended).</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Will they be kept separate from subject data and specimens?</li> <li>• For anonymous studies, it is crucial to keep identifiers separated from the actual data.</li> <li>• Ultimately stored in a locked, password protected file.</li> <li>• For international travel for example, the documents should not ever be left unattended.</li> </ul>
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## Section 9- Study PI(s) Declaration Study PI(s) Declaration

### THE UNT IRB DECLARATION BY ALL INVESTIGATORS:

- This proposal is guided by the ethical principles regarding research involving human subjects as set forth in the [Belmont Report](#).
- I/We agree to abide by the policies and procedures of the IRB at UNT, including obtaining appropriate training in human subject research for myself and those involved in its conduct.
- I/We will not initiate any research associated with this proposal on or off campus until authorized by the IRB.
- I/We will report to the IRB about any adverse events or unanticipated problems (unexpected, possible greater risk, etc.) that occur.
- I/We will inform the IRB of a need to modify the study design requiring an amendment.
- I/We understand that Full Board approval, when granted, is valid for up to one year and will submit a renewal for its continuation if needed.

9.1 The above declaration must be followed by ALL investigators on this study. The individual who completed the protocol must type their name below.

<p>Regardless of who completed the protocol, the System will route the protocol to <b>the lead PI to certify</b>. Signature of the individual who completed this protocol:</p>	<p>If you are the student investigator, please work with your professor to ensure that they know you have completed your protocol in the System.</p>
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For more information visit [UNT IRB website](#).

Contact Research Integrity and Compliance

Email: [UNTIRB@unt.edu](mailto:UNTIRB@unt.edu)

Phone: 940-565-4643